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August 13, 2012

US EPA Office of Pollution Prevention and Toxics EPA East Building Room 6428 Attn: Section 8(e) 1201 Constitution Avenue, NW Washington, DC 20004

Cc: Polymer Chemicals bv
Arkema France
Pergan GmbH
United Initiators GmbH & Co. KG

347877

OPPT CBIC 2012 /JUS 14 ATT 10: 21

**SUBJECT: TSCA 8(e) Notice** 



Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Polymer Chemicals LLC, we are submitting unaudited results on an OECD 422 Combined Repeat Dose, Reproduction/Developmental Toxicity Screening Test with 1,1,3,3-tetramethylbutyl 2-ethylperoxyhexanoate (CAS 22288-43-3). The study was sponsored by Akzo Nobel Polymer Chemicals by.

The test item was administered by gavage to three groups each of ten male and ten female rats, for up to eight weeks, at dose levels of 30, 300 and 1000 mg/kg bw/day. A control group of ten males and ten females were dosed was dosed with vehicle alone (Arachis oil).

Mortality. There were no unscheduled deaths.

<u>Clinical Observations</u>. Animals of either sex treated with 1000 mg/kg bw/day showed episodes of increased salivation from Day 3 onwards. Two males treated with 300 mg/kg bw/day also showed increased salivation on Day 15.

<u>Water Consumption</u>. Animals of either sex treated with 1000 mg/kg bw/day showed an increase in overall water consumption compared to control animals.

<u>Hematology</u>. Males treated with 1000 mg/kg bw/day showed an increase in platelet count. Females treated with 1000 mg/kg bw/day showed reductions in hemoglobin and erythrocyte count and an increase in neutrophil count. Females treated with 300 mg/kg bw/day also showed a reduction in hemoglobin and an increase in neutrophil count. No toxicologically significant effects were detected in males treated with 300 mg/kg bw/day or in animals of either sex treated with 30 mg/kg bw/day.

<u>Blood Chemistry</u>. Males treated with 1000 mg/kg bw/day showed increases in albumin/globulin ratio, alanine aminotransferase and alkaline phosphatase. Males from all treatment groups also showed increases in albumin and creatinine. Females treated with 1000 mg/kg bw/day showed increases in total protein and albumin.



## Reproductive Performance

There were no treatment related reproductive effects.

## <u>Pathology:</u>

Organ Weights. Males treated with 1000 and 300 mg/kg bw/day showed increases in absolute and relative kidney, liver and spleen weight. Females treated with 1000 mg/kg bw/day showed increases in absolute and relative liver and spleen weight. Kidney weights were also increased for females treated with 1000 and 300 mg/kg bw/day.

Necropsy. Six males treated with 1000 mg/kg bw/day had enlarged, pale and mottled kidneys. A further male from this treatment group also had enlarged kidneys. One female treated with 1000 mg/kg bw/day had increased renal pelvic space in the right kidney. At 300 mg/kg bw/day, one male had enlarged and pale kidneys, three males had pale and mottled kidneys, one male had pale kidneys and one male had mottled kidneys.

Histopathology. The following treatment related microscopic abnormalities were detected.

Liver: Centrilobular to diffuse hepatocellular hypertrophy was evident in animals of either sex treated with 1000 mg/kg bw/day.

Kidneys: Nephropathy consisting of increased incidence and severity of hyaline droplets, tubular degeneration, tubular dilation/vacuolation, granulated tubular casts and interstitial inflammatory infiltrate was evident in males treated with 1000 mg/kg bw/day.

Spleen: Slightly increased incidence and/or severity of splenic extramedullary hematopoiesis was evident in animals of either sex treated with 1000 mg/kg bw/day.

Thyroids: Increased incidence and severity of follicular cell hypertrophy was evident in animals of either sex treated with 1000 mg/kg bw/day.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,

Louette Rausch

Expertise Leader Regulatory Affairs Americas

Kausels

Akzo Nobel Services Inc.

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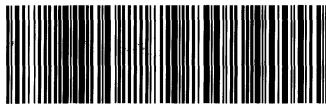
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